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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,809	06/30/2000	GEORGE E. SEIDEL	XY-LODO-USNP	3161

7590 11/06/2002
SANTANGELO LAW OFFICES
125 SOUTH HOWES
THIRD FLOOR
FORT COLLINS, CO 80521

EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,809

Applicant(s)

SEIDEL ET AL.

Examiner

Brian Szmaj

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-29 and 165-173 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-29 and 165-173 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13, 14, 20-22, 24, 28, 170 and 171 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 21, 22 and 24 recite in the preamble "having a predetermined sex", whereas Claim 1 does not recite "having a predetermined sex" in the preamble. Removal of the phrase is requested.

Claim 15 states "sensing a property of said sperm cells", whereas the remainder of the claim cites the sperm cells having a "sex characteristic". It is unclear to the Examiner what the correlation of the "property" is to how the "sex characteristic" is determined. Claim 20 cites "between any of days 2 and 18". It appears this phrase should read as "between any of days 2 to 18". Correction is required.

3. Claim 28 recites the limitation "said collector" in line 3. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 170 recites the limitation "inserting at least a portion of said insemination sample" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 171 recites the limitation "inserting said insemination sample having said low number of said sperm sells" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 2, 5-15, 19, 25 and 169-171 are rejected under 35 U.S.C. 102(a) as being anticipated by Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995).

Seidel et al disclose means for utilizing small dosages of semen to inseminate heifers and further discloses: collecting sperm from a male of the species; establishing a sample having no more than 10% of the number of sperm cells relative to a typical insemination sample; inserting the insemination sample into a female of the species; fertilizing at least one egg at success levels statistically comparable to a typical dosage; producing an offspring mammal; the success levels are at least 35-50%; the insertion of the insemination sample in both ipsi- and contra-lateral within the uterine horns of the mammal; the species has at least one uterine horn; inserting the insemination sample using embryo transport equipment; inserting the sample 12 hours after the time which is regarded as optimal for a single insemination; the insemination occurs no later than 17 hours from the establishment of the semen sample; the insemination occurs no later than 10 hours from the establishment of the semen sample having no more than 50% of the number of sperm cells relative to the typical dosage; determining the characteristic

of a plurality of sperm cells; separating the sperm cells according to the determination of the sex characteristic; establishing a sperm cell source; sensing a property of the sperm cells; discriminating between the sperm cells having a desired sex characteristic; collecting sperm cells having the desired sex characteristic; collecting sperm cells from bovines; using an ovulatory pharmaceutical to cause multiple eggs to be produced; a bovine sample having no more than 250,000 sperm cells; the insemination can be done in field conditions; and inserting a sample having a low number of sperm, a substantial number of which have the desired sex characteristic. See whole document.

Seidel et al establishes 2.5 million sperm as the control, which can be thought of as the typical dosage. Seidel et al also uses a sperm sample of 250,000 in the experiment, which is 10% of the control amount, as well as the statistical success of using a 10% sample. The control success rate was 56%, whereas the success rate of the 10% sample was 52%, which is statistically comparable since it is only a 4% difference. Furthermore, Seidel et al discloses the use of prostaglandin F-2-alpha, a hormone for increasing ovulation.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 16, 17, 20-23, 24, 26 and 165-167 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) as applied to claim 1 above, and further in view of Adair.

Seidel et al, as discussed above, disclose means for low number sperm samples for artificial insemination, but fail to disclose establishing a sheath fluid for the sperm cells; cushioning the sperm cells; staining the sperm cells; the sheath fluid contains sodium citrate; a collection container; and the citrate collection fluid contains egg yolk.

Adair discloses a method of treating collected semen and separating sperm into X and Y components, and further discloses establishing a sheath fluid for the sperm cells; cushioning the sperm cells; staining the sperm cells; the sheath fluid contains sodium citrate; a collection container; and the citrate collection fluid contains egg yolk. See Column 3, lines 14-15 and 25-39; and Column 4, lines 6-54.

Since both Seidel et al and Adair disclose means for using a flow cytometer for separating sperm, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosure of Seidel et al to include the specific steps undertaken during flow cytometer usage, as per the teachings of Adair, since it would permit a separation of bovine sperm such that the offspring can be produced to attain the wanted genetic traits within a male or female bovine. It also would have been obvious to one of ordinary skill in the art to use a 2.9% sodium citrate since Adair discloses a buffer solution containing citrate, but does not disclose the actual concentration. It also would have been obvious to have the citrate solution

contain about 6% egg yolk, since Adair discloses a commercially available solution containing citrate and egg yolk but does not disclose the concentrations in the solution. Claims 20-22 and 167 are obvious engineering design choices if nothing else works.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) as applied to claim 14 above, and further in view of Spaulding ('990).

Seidel et al, as discussed above, disclose means for low number sperm samples for artificial insemination, but fail to disclose the flow cytometer sorting sperm cells at a rate of at least 500 sorts per second.

Spaulding discloses means for increasing the probability that offspring will be a desired sex, and further discloses the flow cytometer sorting sperm cells at a rate of at least 500 sorts per second. See Column 9, lines 45-54.

Since both Seidel et al and Spaulding disclose means for increasing the probability of producing a specific sexed offspring, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose of the rate of the flow cytometer, as per the teachings of Spaulding, since Seidel et al discloses the possible use of a flow cytometer but does not disclose the rate of separation of the sperm cells.

11. Claim 168 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) and Adair as applied to claim 16 above, and further in view of Spaulding ('990).

Seidel et al and Adair, as discussed above, disclose means for separating and inseminating heifers, but fail to disclose the flow cytometer sorting at a rate of at least 1200 sorts per second.

Spaulding, as discussed above, discloses means for increasing the probability that offspring will be a desired sex, and further discloses the flow cytometer sorting sperm cells at a rate of at least 1200 sorts per second. See Column 9, lines 45-54.

Since Seidel et al, Adair and Spaulding disclose means for increasing the probability of producing a specific sexed offspring, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose of the rate of the flow cytometer, as per the teachings of Spaulding, since Seidel et al and Adair disclose the use of a flow cytometer but does not disclose the rate of separation of the sperm cells.

12. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) and Adair as applied to claim 16 above, and further in view of Shrimpton ('177).

Seidel et al and Adair, as discussed above, disclose means for increasing the probability of producing a specific sexed offspring, but fail to disclose a means for avoiding impact of the sperm cells in the collector; and a collection container having a diameter of at least 15 millimeters.

Shrimpton discloses a method for separating sperm cells and further discloses avoiding impact of the sperm cells in the collector; and a collection container having a diameter

of at least 15 millimeters. See Figures 2-4 and 6. Figure 6 shows the collectors are larger than 15 millimeters.

Since Seidel et al, Adair and Shrimpton disclose means for controlling the sex of an offspring, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose means for avoiding impact of sperm cells in the collector and the collector having a minimal size, as per the teachings of Shrimpton, since it is well known in the art that sperm cells are susceptible to damage if the cells are exposed to excess vibration, light, and heat.

13. Claims 27, 172 and 173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seidel et al ("Insemination of Holstein heifers with very low numbers of unfrozen spermatozoa", 1995) as applied to claims 25 and 171 above, and further in view of Seidel et al ("Uterine Horn Insemination of Heifers with Very Low Numbers of Nonfrozen and Sexed Spermatozoa", 1997).

Seidel et al (1995), as discussed above, disclose means for low number sperm samples for artificial insemination, but fail to disclose establishing the sheath fluid that contains a hepes buffered medium.

Seidel et al (1997) discloses means for using small sex-separated semen samples to obtain sex specific offspring and further discloses the use of a hepes buffered medium. See page 1257, last paragraph.

Since both Seidel et al (1995) and Seidel et al (1997) disclose means for using small semen samples to achieve successful insemination, it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose the use of a


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hepes buffered medium, as per the teachings of Seidel et al (1997), since it is well known in the art to use several different types of dilution solutions to achieve the desired viscosity of the semen prior to insemination. It also would have been obvious to one of ordinary skill in the art to use the method of separating sperm to achieve sex specific offspring in other animals, such as pigs and horses since the method for performing the insemination is the same, with the exception for the type of animal it is performed upon.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj who's telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.


BS

October 28, 2002


MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700